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*JFW*  
**PATENT**

Atty. Docket No.  
AR02766USACON2

CN 27777



Date: Aug 31, 2004 By: *[Signature]*

Lois E. Miller

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Atul D. AYER et al.

Serial No.: 10/661,168

Filed: September 12, 2003

For: THERAPEUTIC COMPOSITIONS AND  
DRUG DELIVERY SYSTEM FOR  
ADMINISTERING A DRUG

Group Art Unit: 1615

Examiner: CHANNAVAJJALA, L.S.

**INFORMATION DISCLOSURE  
STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the

*Jur Lee only*

mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner,  
Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in  
accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application  
publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent  
application was filed after June 30, 2003 or this international application has entered the national  
stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR  
1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

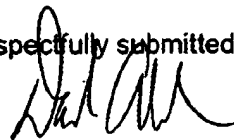
☐ The relevance of those listed references which are not in the English language is  
as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s),  
which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may  
be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,



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